Oct. 9, 1962 A. A. STONEHILL ETAL 3,057,471

ANTI-CONTAMINATION PACKAGE ASSEMBLY FOR SURGICAL SUPPLIES

Filed March 22, 1957 2 Sheets-Sheet 1

Fig. 1.

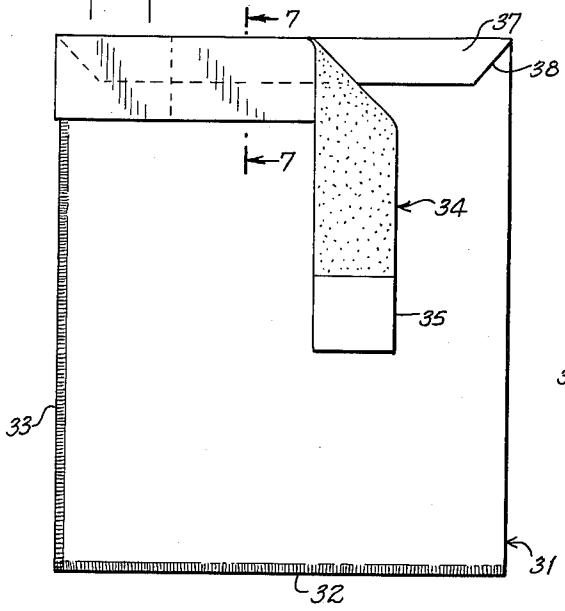


Fig. 2.

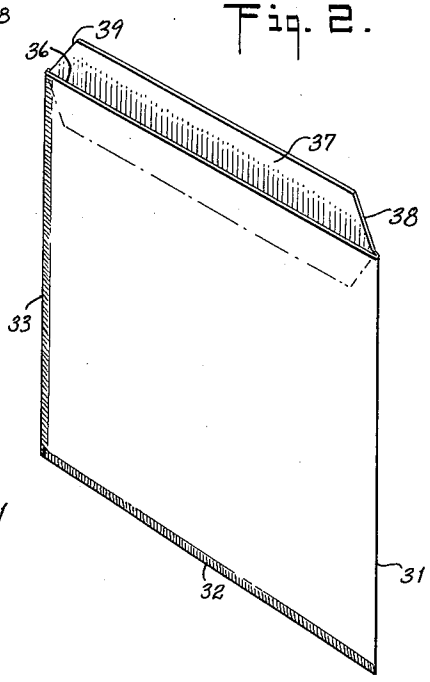
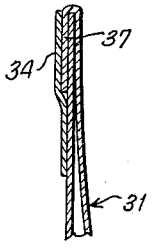


Fig. 3.



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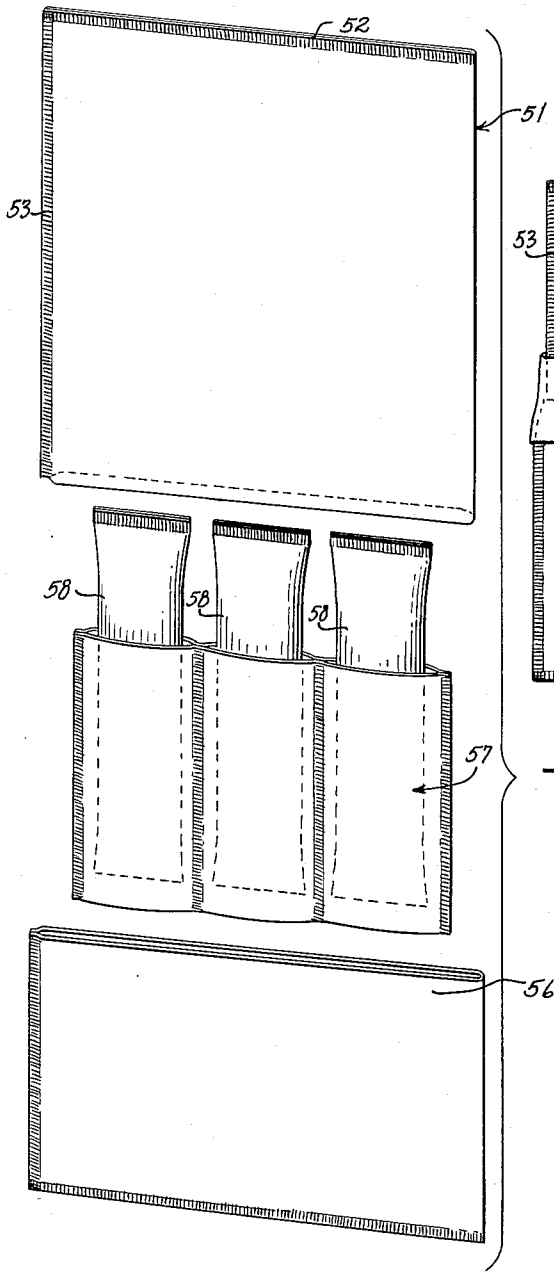
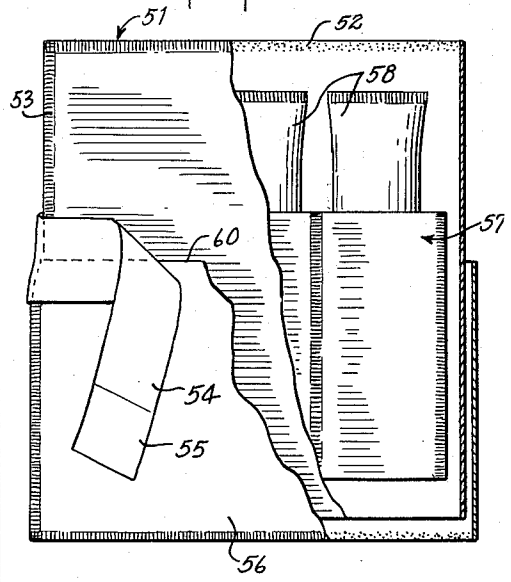


Fig. 5.

Fig. 4.



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ANTI-CONTAMINATION PACKAGE ASSEMBLY FOR SURGICAL SUPPLIES

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Filed Mar. 22, 1957, Ser. No. 647,790
4 Claims. (Cl. 206—63.3)

This invention relates to a package assembly for surgical supplies wherein the possibility of contamination of the contents by opening the package is avoided, and more particularly to such a package assembly wherein a sterile zone is maintained around the opening of the package to avoid the possibility of contamination of the contents from the outer surface of the package.

Modern aseptic techniques in surgical operations require elaborate precautions to prevent entrance of contaminated objects into the operating area of the operating room. Not only must all objects brought into the area have been sterilized, no object should be brought within the operating area which has come in contact with a non-sterile article.

To carry out these rigorous precautions it is customary to employ a circulating nurse in the operating room. It is the function of the circulating nurse to operate outside of the immediate operating area to bring whatever articles are needed into the immediate area of the operating table. The entire area of the operating room is of course scrupulously clean by ordinary standards, but obviously the entire room cannot be sterilized and thus the circulating nurse must consider her gloves and the surfaces that she handles with her gloves to be contaminated. The circulating nurse therefore employs sterilized trays and sterilized instruments to convey articles into the sterile zone surrounding the operating table and thus to maintain their sterility.

Another nurse is employed in the immediate area of the operating table who is called the sterile nurse. Since she does not leave the immediate area of the operating table and does not touch any article which might be contaminated, she may directly handle instruments, sutures and the like in assisting the surgical operation. It will be obvious that this rather elaborate scheme provides a very effective method of insuring that contamination introduced by transfer from one article to another is not brought within the immediate area of the operating table.

It will be readily understood from the foregoing description of the operating room procedure that the mere packaging of a surgical supply within a container having a sterile interior will not provide a solution to the problem of eventually supplying to the actual operating area an article in sterile condition. The outside of the package must necessarily be considered to be contaminated. Therefore the package cannot be brought within the operating area.

On the other hand, if the package is cut open there is great likelihood that contamination will be transferred to the inner surface of the package and subsequently to the contents of the package. Furthermore, the package must be such that no possibility of contact between the contents and any portion of the outside of the package can occur.

A packaging arrangement which met with these requirements is shown in U.S. Patent No. 2,470,494 to A. B. Kennison. The Kennison patent shows a large container having a number of glass tubes therein, each tube containing an individual surgical suture. The tubes are covered with a sterilizing solution such as an alcohol formaldehyde solution. Utilizing the Kennison arrangement, the non-sterile outer container is maintained outside the operating area and the glass tubes are removed

from the container by means of sterile tongs or by other such sterile technique. They are transported to the sterile operating area by the circulating nurse also by means of a sterile tongs, tray, or the like.

The glass tubes having been in the sterilized solution are sterile on the outside, and of course, have previously been sterilized on the inside so that the article is brought within the operating area in a sterile condition. Further precautions are taken to reduce airborne contamination but these precautions need not be explained in detail here.

The glass tubes having been brought into the sterile operating area may then be broken by the sterile nurse to obtain the suture contained therein and thus a factory sterilized suture is supplied to the operating area in a manner which preserves its sterility and the sterility of the operating area to the highest degree possible.

It will be obvious however that certain disadvantages accrue from the necessity of maintaining a container of liquid within the operating room and the necessity of having broken glass in the operating area. The present invention provides an anti-contamination package assembly for surgical supplies which does not require a sterilizing fluid, which is unbreakable, compact, and convenient.

It is accordingly an object of the present invention to provide a package assembly for surgical supplies which is capable of being opened without causing transfer of contamination from the non-sterile portion of the outer surface of the package to the uncontaminated contents of the package.

It is another object of the present invention to provide a package assembly for surgical supplies wherein a sterile zone is maintained about the opening or mouth of the container so that the contents of a container may be removed without the possibility of causing transfer of contamination from the outer portion of the container to the uncontaminated contents of the container.

It is another object of the present invention to provide an anti-contamination package assembly for surgical supplies which may be opened by tearing an adhesive strip from the mouth of the package.

It is still another object of the present invention to provide an anti-contamination package assembly for surgical supplies having a flap covering the opening, said flap being maintained in a sterile condition so that when the contents of the package are removed by sliding over the flap, there is no possibility of contamination of the uncontaminated contents.

It is a still further object of the present invention to provide an anti-contamination package assembly for surgical supplies consisting of two envelopes fitted together in telescoping fashion to provide a closed container so that the inside envelope has a sterile zone surrounding its mouth to avoid the possibility of contamination in the withdrawal of the contents from the inside envelope.

Other objects and advantages will be apparent from a consideration of the following description in conjunction with the appended drawings, in which:

FIG. 1 is a plan view of a package according to the present invention;

FIG. 2 is a perspective view of the device of FIG. 1 after it has been opened;

FIG. 3 is a vertical sectional view of the package of FIG. 1 taken along the line 7—7 in FIG. 1;

FIG. 4 is a plan view of an alternative embodiment of the present invention partially cut away to show the elements of the package; and

FIG. 5 is an exploded view of the package of FIG. 4 illustrating the method of removal of the contents of the package.

Referring to FIGS. 1, 2 and 3, a container 31 is shown

illustrated as a flexible plastic envelope. Container **31** may be constructed, for example, by folding and sealing at edges **32** and **33**. It is contemplated that the best arrangement for the container **31** would consist of an envelope formed of a flexible transparent material. Container **31** might be formed for example of polyethylene or of materials sold under the trademarks "Mylar," "Nylon," "Cellophane" or "Saran."

It is an advantage of the present invention that a relatively inexpansive material could be used for container **31**. If a plastic container were to be used in accordance with the teachings of the patent to Kennison where the package was maintained in an alcohol formaldehyde solution, the plastic would have to be relatively unaffected and impermeable to formaldehyde. Although such a plastic is known (monochlorotrifluoroethylene, for example, sold under the trade-marks "Genetron" and "Kel-F"), known formaldehyde resistant plastics are so expensive that their use is practically prohibitive. Since the present invention does not require that the container **11** be formaldehyde resistant, any one of a number of inexpensive plastics may be used.

Although a preferred embodiment of the container is illustrated, namely, a flexible transparent plastic container, it should be understood that the invention is not limited to containers having either of the qualities of flexibility or transparency. Metal in the form of foil or in other form could be used for example. The container **31** of FIG. 1 may be sealed along edges **32** and **33** by the application of heat or the container **31** may be formed in any other fashion. Only one adhesive strip **34** is utilized in the package of FIG. 1. The adhesive strip **34** extends across the front of the container **31** and may also be folded around the end of the container at the opposite side. The end of the strip **34** is provided with a non-adhesive portion **35**. This portion may be formed by folding over the adhesive strip **34**, if desired. The opening **36** of the container **31** is closed by a flap **37** which is folded over the front of the container **31**.

The adhesive tape **34** is applied over the flap **37** and extends downward over a portion of the front of the container **31**. The corners of the flap **37** may be cut off as shown at **38** and **39** to allow the tape **34** to fit more smoothly around the edges of the container **31**.

Adhesive tape sold under the trademark "Permacel" has been found satisfactory to provide a reliable seal against contamination for the package of FIGURES 1–3.

The manner in which the package of FIGS. 1 to 3 may be utilized will now be explained. Packages such as that shown in FIG. 1 would be stored in the operating room in a location beyond the immediate area of the operating table. It would be the responsibility of the circulating nurse to open the outside container **31** and withdraw the sterile contents of the container. The circulating nurse would accomplish this by grasping the tape strip **34** and pulling the tape off the container **31**. The condition of the container after the tape strip **34** is removed is indicated in FIG. 2. The circulating nurse would remove the contents of the container **31** without touching them by means of a sterilized instrument or else by dumping them out or by squeezing them out onto a sterilized tray.

The circulating nurse would then transport the contents of the package **31** on the tray or by means of the instrument to the sterile area surrounding the operating table where they would be conveyed to the sterile nurse or left in the location within the reach of the sterile nurse.

It is important to note that some such sealing means as the adhesive tape **34** is a novel and essential feature of the present invention. Suppose for example that the container **31** were simply sealed on all four sides and that the container were opened by cutting with scissors, for example. Even if the scissors were sterile, it is obvious that in the act of cutting, the blades of the scissors would come in contact with the outer surface of the container and in cutting through the container would transfer contamination from the outer surface to the inner surface of the container **31**. Thereafter when the contents of the container were withdrawn, contamination transferred to the inner surface of the container could further be transferred to the contents of the container itself. The same thing would be true if the container were cut or torn open other than by scissors.

The adhesive tape seal shown in FIGS. 1 and 3 may be torn open without tarnsferring contamination to the interior surface of the container **31**. Furthermore, the adhesive seal strip **34** not only seals the interior of the container but also protects an area surrounding the mouth **36** of the container from contamination. This provides a zone around the mouth of the container **31** which is uncontaminated thus further insuring that the contents of the container **31** will not be drawn over a contaminated surface in the process of removal from the container.

A further advantage accrues from the foregoing packaging arrangement where the container **31** and tape **34** are made of a material which is penetrable to electron beam radiation. In this case the entire package can be assembled in a non-sterile condition and can thereafter be subjected to electron beam radiation to sterilize the contents and the entire unexposed surface of the package. This method of packaging is extremely desirable since the entire packaging procedure can be accomplished without the necessity of any precautions to maintain sterility.

Although electron beam radiation is particularly desirable as a sterilizing method for packages according to the present invention, it should be understood that other sterilizing methods using heat or a sterilizing gas, or vapor, for example, might be employed.

An alternative embodiment of the present invention is shown in FIGS. 4 and 5 which is characterized by the fact that two envelope type containers are telescoped to provide a single sealed container. A first long envelope **51** may be formed by folding and sealing a plastic sheet at **52** and **53** as previously explained or may of course be formed in any other suitable manner. A second short envelope **56** is placed over the envelope **51**, the open ends facing together. The package may be sealed by sealing together the outer envelope **56** and the inner envelope **51** around the periphery of the container.

An adhesive tape **54** is illustrated in FIG. 4 as one means of sealing the respective envelopes **51** and **56**. The tape **54** may be provided with a non-adhesive portion **55** as a tab for opening the container in the manner previously explained. It should be noted, however, that the utilization of tape such as **54** is not the only arrangement by which the advantages of the present invention may be obtained. It may particularly be noted in connection with FIG. 4 that the tape **54** rather than being adhesive tape could be flexible tape of a material similar to that used for the envelopes **51** and **56** but of substantially lesser thickness or of substantially less tensile strength. Such a tape could then be permanently sealed rather than adhesively sealed to the envelopes **51** and **56** in the same position as that occupied by the tape **54** in FIG. 4. The package in FIG. 4 could then be opened by pulling apart the envelopes **51** and **56** to break or tear the non-adhesive tape.

Many other equivalent arrangements could be utilized to provide a readily partable seal between the envelope **51** and the envelope **56**. As a further example, the top edge **60** of the envelope **56** could be directly sealed to the envelope **51** and a weakened portion could be provided in the container either at the point of sealing or adjacent the point of sealing in the envelope **56**. Thus a readily partable seal could be provided without the utilization of any tape whatsoever. The packet **57** and capsules **58** for further packaging the sutures may be utilized if desired in conjunction with the container of FIG. 4.

The present invention therefore provides a package for

surgical supplies which is particularly effective in reducing the likelihood of contamination of such supplies, which is of relatively simple and inexpensive construction, and which is very convenient to open and use.

Numerous modifications of the packaging arrangement shown have been suggested. However, it will be obvious that many other modifications could be made within the scope of the invention. The scope of the invention is therefore not to be construed to be limited to the particular embodiments shown or suggested, but is rather to be limited solely by the appended claims.

What is claimed is:

1. A package assembly capable of being opened without causing transfer of contamination from the non-sterile portion of the outer surface of the package to the sterile contents of the package, said package comprising two substantially flat envelopes formed of flexible sheet material permeable to electron beam radiation but impermeable to microorganisms, the first of said envelopes having an open end, the second of said envelopes fitting over the open end of said first envelope and having an opening defined by closely spaced and substantially coinciding edges, a strip of adhesive tape joining the periphery of said second envelope to said first envelope along a line intermediate the open end and the opposite end of said first envelope, said strip completely enclosing the edges of the last said opening and confining said edges against the inner face of the strip, and contents within said first envelope, the interior portion of said envelope, the portion of the exterior of said envelope covered by said tape and the contents of said envelope being in a sterile condition whereby the act of opening said package does not transfer contamination to the sterile inner surface of said first envelope and the open end of said first envelope is provided with a sterile zone adjacent thereto to prevent contamination of the contents of the container upon removal from the container.

2. A package assembly capable of being opened without causing transfer of contamination from the non-sterile portion of the outer surface of the package to the uncontaminated contents of the package, said package comprising a substantially flat container of flexible sheet material, said package being formed of two open-ended envelopes with the second envelope placed over the open end of the first envelope and said second envelope having an opening defined by straight substantially coinciding edges; a readily removable closure sealing said second envelope opening, said closure comprising at least one strip, said strip completely enclosing the edges of the last said opening and confining the edges against the inner face of the strip and in spaced relation to the edges of the strip, said strip further being arranged to cover and seal a band of the exterior surface of said container completely surrounding and adjacent to the edges of the last said opening against the ingress of microorganisms, said strip being longitudinally strippable relative to the edge of the last said opening and sealed together beyond the ends of the edges of the last said opening; and contents in said package, the interior portion of said container, the portion of the exterior of said container, covered by said strip, and said contents of said package being in a sterile condition; whereby the act of opening said container does not transfer contamination to the uncontaminated inner surface of said container and the opening of said container is provided with an uncontaminated zone adjacent thereto to prevent contamination of the outer surface of the contents of the container upon removal from the container.

3. A package assembly capable of being opened without causing transfer of contamination from the non-sterile portion of the outer surface of the package to the uncontaminated contents of the package, said package comprising a substantially flat container of flexible sheet material having an opening defined by a straight edge and a flap of a length approximately equal to said edge and adapted to fold over said edge; a readily removable closure hermetically sealing said opening, said closure comprising at least one strip, said strip completely enclosing the edges of the opening and confining the edge of said flap against the face of the strip and in spaced relation to and between the edges of the strip, said strip further being arranged to cover and seal a band of the exterior surface of said container completely surrounding and adjacent to the edges of said opening against the ingress of microorganisms, said strip being longitudinally strippable relative to the edge of said opening and sealed together beyond the ends of the edges of said opening with the parting line between the edge of said strip and the remainder of said package being located centrally of said container with respect to said opening; and contents in said package, the interior portion of said container, the portion of the exterior of said container, covered by said strip and said contents of said package being in a sterile condition; whereby the act of opening said container does not transfer contamination to the uncontaminated inner surface of said container and the opening of said container is provided with an uncontaminated zone adjacent thereto to prevent contamination of the outer surface of the contents of the container upon removal from the container.

4. An envelope for containing an article in sterile condition, said envelope being composed of thin flexible material impermeable to microorganisms and comprising a body section adapted to receive a sterile article and having sealed side and bottom edges and an open mouth at its upper end, a closure section adapted to telescope over the upper end of the body section and having sealed side and top edges, means for sealing said closure to said body section near the bottom edge of said closure to seal a band of the exterior surface of said body section completely surrounding and adjacent said open mouth against the ingress of microorganisms, said sealing means including a flexible element for strippably separating at least a portion of said closure from said body section along a parting line located below the open mouth of said envelope, and contents in said package.

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UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,057,471 October 9, 1962

Albert A. Stonehill et al.

It is hereby certified that error appears in the above numbered patent requiring correction and that the said Letters Patent should read as corrected below.

Column 3, line 10, for "inexpansive" read -- inexpensive --; column 6, under the heading "UNITED STATES PATENTS" add the following:

2,355,786	Dreher et al. -----	Aug. 15, 1944
2,697,531	Hood ----------	Dec. 21, 1954

Signed and sealed this 12th day of March 1963.

(SEAL)
Attest:

ESTON G. JOHNSON
Attesting Officer

DAVID L. LADD
Commissioner of Patents